K121328

ELEKTA

JUN 12 2012

510(k) SUMMARY

Date of preparation of summary: 27th April 2012

Submitted by:

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Contact name: Patrick Hull

Trade Name:	Agility™
Common Name:	Multileaf Collimator
Classification Name:	Medical Linear Accelerator Accessory, 21CFR 892.5050
Product Code:	IYE
Predicate Device:	MLCi2 (K082122)

Product Description:

This Traditional 510(k) describes the addition of the new Agility multileaf collimator beam limiting device and its associated control software to the Elekta medical linear accelerator. The new device has 160 leaves of 5mm width at isocenter, a fast leaf speed of up to 65 mm/s, low leakage (<0.5%) and is capable of interdigitation within a maximum field size of 40 x 40 cm. Control is by extension to the existing Elekta linear accelerator control system software. Synchronization of the movement of the dynamic leaf guides with individual leaf movements achieves enhanced leaf speed and removes the need for a split field.

Indications For Use and Intended Use Statement:

The Agility multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.

The associated Integrity R3.0 software is the interface and control software for the Elekta range of medical digital linear accelerators and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions, delivered as static and/or dynamic beams of radiation, in all areas of the body where such treatment is indicated.

Summary of Technological Characteristics:

Agility™ is a new multileaf collimator with a dedicated linac control system.

The Agility includes dynamic leaf guides, fluorescing ruby leaf markers ('Rubicon') for improved leaf tracking by the optics system, the elimination of backup diaphragms by providing low inter-leaf leakage, sculpted field defining diaphragms, separate lighting systems for patient plane illumination and movement control using LEDs, and a new control cabinet on which the Integrity user interface and machine control software is executed including a hardware firewall to provide safe network connection.

There are no novel forms of technology introduced by this device.

Substantial Equivalence

The functionality of the Elekta medical linear accelerator with Agility™ is substantially equivalent to that of its predicate device, MLCi2 (K082122), in safety and effectiveness. The intended use, principles of operation, technological characteristics and labelling are substantially equivalent.

The primary differences between the predicate device and the new device are the improved resolution across the 40cm x 40cm field size provided by the 5mm leaf width at isocenter, faster leaf and diaphragm speeds, and longer diaphragm over-travel. It does not directly introduce additional clinical functionality.

Attributes	Elekta linac with Agility & Integrity R3.0 (this submission)	Elekta linac with MLCi2 & Integrity R1.1 (K802122)
Mechanical		
Interdigitation capable	yes	yes
Number of leaves	160	80
Nominal leaf width projection at isocenter	5 mm	10 mm
Maximum field size	40 x 40 cm	40 x 40 cm
Maximum distance between leaves on the same leaf guide	20 cm	32.5 cm
Leaf travel over central axis	15 cm	12.5 cm
Leaf nominal height	90 mm	82 mm
Leaf positioning resolution	0.1 mm	0.1 mm
Leaf positioning verification method	Optical and machine vision system (Rubicon)	Optical and machine vision system
Diaphragm over-travel	12 cm	0
Dimensions / Weight / Speeds		
Head rotation	365 degrees	365 degrees
Head weight	420 kg	380 kg
Radiation head diameter	815 mm at the widest, 694 mm at the narrowest	620 mm
Head to isocenter clearance	45 cm	45 cm
Head rotation speed for set-up	12°/s	12°/s
Head rotation speed for dynamic delivery techniques	6°/s	6°/s
Leaf speed combined with the dynamic leaf guide	up to 6.5 cm/s	2.0 cm/sec
Leaf speed	up to 3.5 cm/s	2.0 cm/sec
Diaphragm speed	up to 9 cm/s	1.5 cm/s
Wedge		
Integrated wedge size	Automatic 0-60°	Automatic 0-60°
Wedge field size	30 x 40 cm	30 x 40 cm
Physics Performance		
Leaf position accuracy	1 mm at isocenter 0.5 mm RMS*	± 1 mm
Leaf position repeatability	0.5 mm	0.5 mm
Average transmission through leaf bank	<0.375%	1.5%
Peak transmission through leaf bank	<0.5%	2.1%
X-radiation leakage in patient plane outside collimator cone	<0.2% max, <0.1% avg.	<0.2% max; <0.1% avg.
X-radiation leakage outside patient plane	<0.5% (at 1 m)	<0.5%

Delivery techniques		
Dynamic Delivery Capability, sliding window	yes	yes
Dynamic Delivery Capability, dynamic arc	yes	yes
Dynamic Delivery Capability, VMAT	yes	yes
Multiple island shielding	yes	yes
Offset field shaping	yes	yes

* measured using stripe test

** information from official product data - the test method may not be equivalent

*** information from official product data - the test standard not specified

Summary of non clinical performance testing

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new and existing features against the requirement specification.

Regression testing has been performed successfully to verify the integrity of any changes.

Validation of the system under clinically representative conditions has been performed by competent and professionally qualified personnel. Results from verification and validation testing demonstrate that conformance to applicable technical design specifications have been met and assured safety & effectiveness as been achieved.

Testing has been undertaken on production equivalent systems both at Elekta and at hospital sites.

The system is subject to compliance testing to voluntary consensus safety standards. Details of the standards employed in the design are specified in the Standard Data Report in section 9 which includes but not limited to IEC 60601-1, IEC 60601-2-1, IEC 60601-1-2, IEC 62304, IEC 62366 and ISO 14971.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Patrick Hull
Regulatory Affairs and Compliance Specialist
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UNITED KINGDOM

JUN 12 2012

Re: K121328
Trade/Device Name: Agility
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 30, 2012
Received: May 3, 2012

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Agility**

Indications for Use: The Agility multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.
The associated Integrity R3.0 software is the interface and control software for the Elekta medical digital linear accelerator and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions, delivered as static and/or dynamic beams of radiation, in all areas of the body where such treatment is indicated.

Prescription Use __✓__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121328